BS EN ISO 9001:2008

BSI British Standards

Quality management systems – Requirements

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National foreword

This British Standard is the UK implementation of EN ISO 9001:2008. It supersedes BS EN ISO 9001:2000 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee QS/1, Quality management and quality assurance procedures.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Qualitätsmanagementsysteme - Anforderungen (ISO 9001:2008)

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Foreword

This document (EN ISO 9001:2008) has been prepared by Technical Committee ISO/TC 176 "Quality management and quality assurance".

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2009, and conflicting national standards shall be withdrawn at the latest by May 2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 9001:2000.

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Endorsement notice

The text of ISO 9001:2008 has been approved by CEN as EN ISO 9001:2008 without any modification.

BS EN ISO 9001:2008

INTERNATIONAL STANDARD

ISO 9001

Fourth edition
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Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This fourth edition cancels and replaces the third edition (ISO 9001:2000), which has been amended to clarify points in the text and to enhance compatibility with ISO 14001:2004.

Details of the changes between the third edition and this fourth edition are given in Annex B.

Introduction

0.1 General

The adoption of a quality management system should be a strategic decision of an organization. The design and implementation of an organization's quality management system is influenced by

a) its organizational environment, changes in that environment, and the risks associated with that environment,

b) its varying needs,

c) its particular objectives,

d) the products it provides,

e) the processes it employs,

f) its size and organizational structure.

It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.

The quality management system requirements specified in this International Standard are complementary to requirements for products. Information marked "NOTE" is for guidance in understanding or clarifying the associated requirement.

This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.

The quality management principles stated in ISO 9000 and ISO 9004 have been taken into consideration during the development of this International Standard.

0.2 Process approach

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system, such an approach emphasizes the importance of

a) understanding and meeting requirements,

b) the need to consider processes in terms of added value,

c) obtaining results of process performance and effectiveness, and

d) continual improvement of processes based on objective measurement.

The model of a process-based quality management system shown in Figure 1 illustrates the process linkages presented in Clauses 4 to 8. This illustration shows that customers play a significant role in defining requirements as inputs. Monitoring of customer satisfaction requires the evaluation of information relating to customer perception as to whether the organization has met the customer requirements. The model shown in Figure 1 covers all the requirements of this International Standard, but does not show processes at a detailed level.

NOTE In addition, the methodology known as "Plan-Do-Check-Act" (PDCA) can be applied to all processes. PDCA can be briefly described as follows.

Plan: establish the objectives and processes necessary to deliver results in accordance with customer requirements and the organization's policies.

Do: implement the processes.

Check: monitor and measure processes and product against policies, objectives and requirements for the product and report the results.

Act: take actions to continually improve process performance.

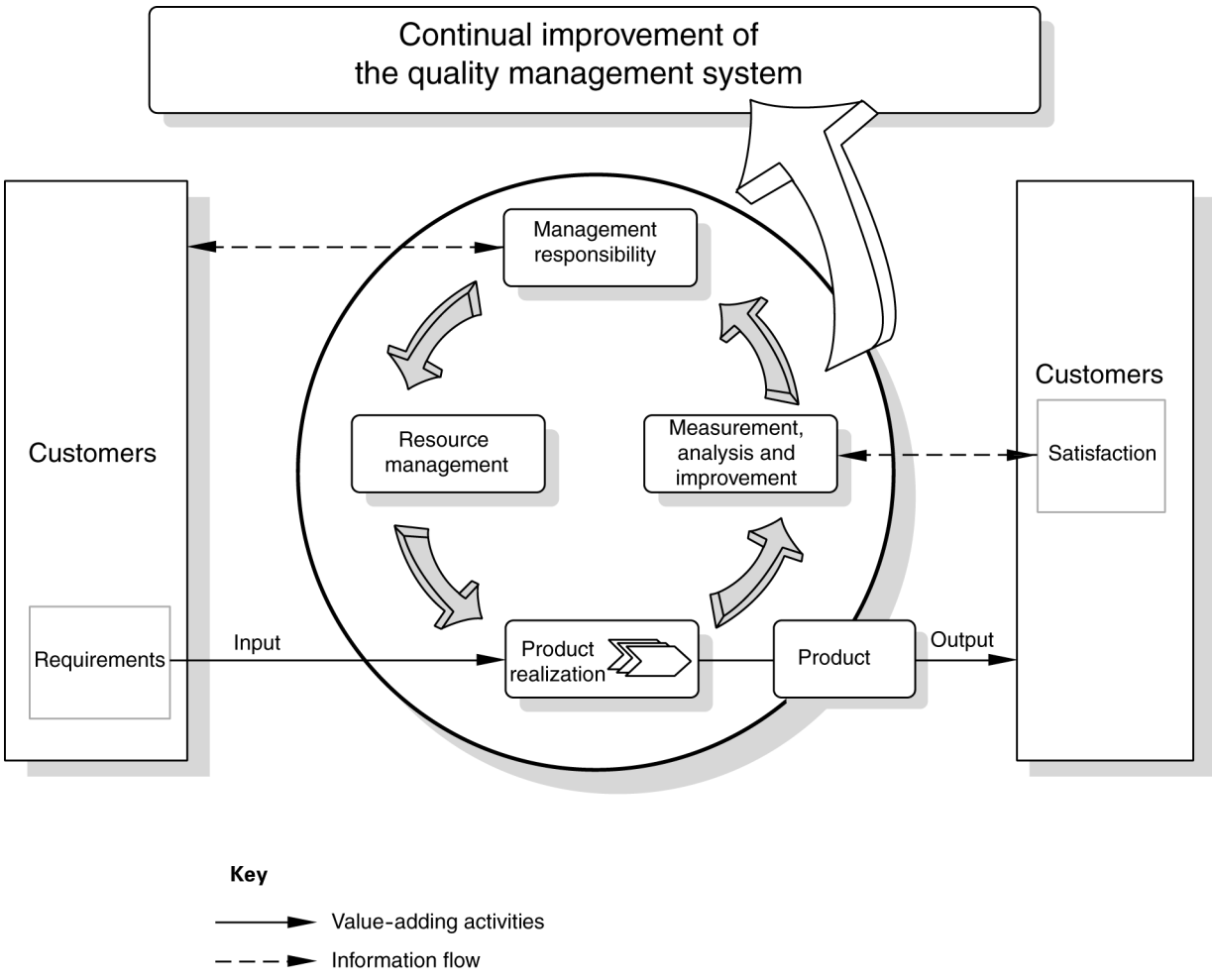

Figure 1 — Model of a process-based quality management system

0.3 Relationship with ISO 9004

ISO 9001 and ISO 9004 are quality management system standards which have been designed to complement each other, but can also be used independently.

ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes. It focuses on the effectiveness of the quality management system in meeting customer requirements.

At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.

0.4 Compatibility with other management systems

During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.

This International Standard does not include requirements specific to other management systems, such as those particular to environmental management, occupational health and safety management, financial management or risk management. However, this International Standard enables an organization to align or integrate its own quality management system with related management system requirements. It is possible for an organization to adapt its existing management system(s) in order to establish a quality management system that complies with the requirements of this International Standard.

Quality management systems — Requirements

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

a) product intended for, or required by, a customer,

b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

1.2 Application

All requirements of this International Standard are generic and are intended to be applicable to all organizations, regardless of type, size and product provided.

Where any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion.

Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2005, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 apply.

Throughout the text of this International Standard, wherever the term "product" occurs, it can also mean "service".

4 Quality management system

4.1 General requirements

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.

The organization shall

a) determine the processes needed for the quality management system and their application throughout the organization (see 1.2),

b) determine the sequence and interaction of these processes,

c) determine criteria and methods needed to ensure that both the operation and control of these processes are effective,

d) ensure the availability of resources and information necessary to support the operation and monitoring of these processes,

e) monitor, measure where applicable, and analyse these processes, and

f) implement actions necessary to achieve planned results and continual improvement of these processes.

These processes shall be managed by the organization in accordance with the requirements of this International Standard.

Where an organization chooses to outsource any process that affects product conformity to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.

NOTE 1 Processes needed for the quality management system referred to above include processes for management activities, provision of resources, product realization, measurement, analysis and improvement.

NOTE 2 An “outsourced process” is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.

NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as

a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements,

b) the degree to which the control for the process is shared,

c) the capability of achieving the necessary control through the application of 7.4.

4.2 Documentation requirements

4.2.1 General

The quality management system documentation shall include

a) documented statements of a quality policy and quality objectives,

b) a quality manual,

c) documented procedures and records required by this International Standard, and

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.

NOTE 2 The extent of the quality management system documentation can differ from one organization to another due to

a) the size of organization and type of activities,

b) the complexity of processes and their interactions, and

c) the competence of personnel.

NOTE 3 The documentation can be in any form or type of medium.

4.2.2 Quality manual

The organization shall establish and maintain a quality manual that includes

a) the scope of the quality management system, including details of and justification for any exclusions (see 1.2),

b) the documented procedures established for the quality management system, or reference to them, and

c) a description of the interaction between the processes of the quality management system.

4.2.3 Control of documents

Documents required by the quality management system shall be controlled. Records are a special type of document and shall be controlled according to the requirements given in 4.2.4.

A documented procedure shall be established to define the controls needed

a) to approve documents for adequacy prior to issue,

b) to review and update as necessary and re-approve documents,

c) to ensure that changes and the current revision status of documents are identified,

d) to ensure that relevant versions of applicable documents are available at points of use,

e) to ensure that documents remain legible and readily identifiable,

f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and

g) to prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for any purpose.

4.2.4 Control of records

Records established to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled.

The organization shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention and disposition of records.

Records shall remain legible, readily identifiable and retrievable.

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

5.2 Customer focus

Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction (see 7.2.1 and 8.2.1).

5.3 Quality policy

Top management shall ensure that the quality policy

a) is appropriate to the purpose of the organization,

b) includes a commitment to comply with requirements and continually improve the effectiveness of the quality management system,

c) provides a framework for establishing and reviewing quality objectives,

d) is communicated and understood within the organization, and

e) is reviewed for continuing suitability.

5.4 Planning

5.4.1 Quality objectives

Top management shall ensure that quality objectives, including those needed to meet requirements for product [see 7.1 a)], are established at relevant functions and levels within the organization. The quality objectives shall be measurable and consistent with the quality policy.

5.4.2 Quality management system planning

Top management shall ensure that

a) the planning of the quality management system is carried out in order to meet the requirements given in 4.1, as well as the quality objectives, and

b) the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and authority

Top management shall ensure that responsibilities and authorities are defined and communicated within the organization.

5.5.2 Management representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained,

b) reporting to top management on the performance of the quality management system and any need for improvement, and

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

5.5.3 Internal communication

Top management shall ensure that appropriate communication processes are established within the organization and that communication takes place regarding the effectiveness of the quality management system.

5.6 Management review

5.6.1 General

Top management shall review the organization's quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews shall be maintained (see 4.2.4).

5.6.2 Review input

The input to management review shall include information on

a) results of audits,

b) customer feedback,

c) process performance and product conformity,

d) status of preventive and corrective actions,

e) follow-up actions from previous management reviews,

f) changes that could affect the quality management system, and

g) recommendations for improvement.

5.6.3 Review output

The output from the management review shall include any decisions and actions related to

a) improvement of the effectiveness of the quality management system and its processes,

b) improvement of product related to customer requirements, and

c) resource needs.

6 Resource management

6.1 Provision of resources

The organization shall determine and provide the resources needed

a) to implement and maintain the quality management system and continually improve its effectiveness, and

b) to enhance customer satisfaction by meeting customer requirements.

6.2 Human resources

6.2.1 General

Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, training, skills and experience.

NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

6.2.2 Competence, training and awareness

The organization shall

a) determine the necessary competence for personnel performing work affecting conformity to product requirements,

b) where applicable, provide training or take other actions to achieve the necessary competence,

c) evaluate the effectiveness of the actions taken,

d) ensure that its personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives, and

e) maintain appropriate records of education, training, skills and experience (see 4.2.4).

6.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements. Infrastructure includes, as applicable,

a) buildings, workspace and associated utilities,

b) process equipment (both hardware and software), and

c) supporting services (such as transport, communication or information systems).

6.4 Work environment

The organization shall determine and manage the work environment needed to achieve conformity to product requirements.

NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).

7 Product realization

7.1 Planning of product realization

The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system (see 4.1).

In planning product realization, the organization shall determine the following, as appropriate:

a) quality objectives and requirements for the product;

b) the need to establish processes and documents, and to provide resources specific to the product;

c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;

d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.4).

The output of this planning shall be in a form suitable for the organization's method of operations.

NOTE 1 A document specifying the processes of the quality management system (including the product realization processes) and the resources to be applied to a specific product, project or contract can be referred to as a quality plan.

NOTE 2 The organization may also apply the requirements given in 7.3 to the development of product realization processes.

7.2 Customer-related processes

7.2.1 Determination of requirements related to the product

The organization shall determine

a) requirements specified by the customer, including the requirements for delivery and post-delivery activities,

b) requirements not stated by the customer but necessary for specified or intended use, where known,

c) statutory and regulatory requirements applicable to the product, and

d) any additional requirements considered necessary by the organization.

NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

7.2.2 Review of requirements related to the product

The organization shall review the requirements related to the product. This review shall be conducted prior to the organization's commitment to supply a product to the customer (e.g. submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders) and shall ensure that

a) product requirements are defined,

b) contract or order requirements differing from those previously expressed are resolved, and

c) the organization has the ability to meet the defined requirements.

Records of the results of the review and actions arising from the review shall be maintained (see 4.2.4).

Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by the organization before acceptance.

Where product requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead the review can cover relevant product information such as catalogues or advertising material.

7.2.3 Customer communication

The organization shall determine and implement effective arrangements for communicating with customers in relation to

a) product information,

b) enquiries, contracts or order handling, including amendments, and

c) customer feedback, including customer complaints.

7.3 Design and development

7.3.1 Design and development planning

The organization shall plan and control the design and development of product.

During the design and development planning, the organization shall determine

a) the design and development stages,

b) the review, verification and validation that are appropriate to each design and development stage, and

c) the responsibilities and authorities for design and development.

The organization shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.

Planning output shall be updated, as appropriate, as the design and development progresses.

NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.

7.3.2 Design and development inputs

Inputs relating to product requirements shall be determined and records maintained (see 4.2.4). These inputs shall include

a) functional and performance requirements,

b) applicable statutory and regulatory requirements,

c) where applicable, information derived from previous similar designs, and

d) other requirements essential for design and development.

The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.

7.3.3 Design and development outputs

The outputs of design and development shall be in a form suitable for verification against the design and development input and shall be approved prior to release.

Design and development outputs shall

a) meet the input requirements for design and development,

b) provide appropriate information for purchasing, production and service provision,

c) contain or reference product acceptance criteria, and

d) specify the characteristics of the product that are essential for its safe and proper use.

NOTE Information for production and service provision can include details for the preservation of product.

7.3.4 Design and development review

At suitable stages, systematic reviews of design and development shall be performed in accordance with planned arrangements (see 7.3.1)

a) to evaluate the ability of the results of design and development to meet requirements, and

b) to identify any problems and propose necessary actions.

Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed. Records of the results of the reviews and any necessary actions shall be maintained (see 4.2.4).

7.3.5 Design and development verification

Verification shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the design and development outputs have met the design and development input requirements. Records of the results of the verification and any necessary actions shall be maintained (see 4.2.4).

7.3.6 Design and development validation

Design and development validation shall be performed in accordance with planned arrangements (see 7.3.1) to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known. Wherever practicable, validation shall be completed prior to the delivery or implementation of the product. Records of the results of validation and any necessary actions shall be maintained (see 4.2.4).

7.3.7 Control of design and development changes

Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).

7.4 Purchasing

7.4.1 Purchasing process

The organization shall ensure that purchased product conforms to specified purchase requirements. The type and extent of control applied to the supplier and the purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.

The organization shall evaluate and select suppliers based on their ability to supply product in accordance with the organization's requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained (see 4.2.4).

7.4.2 Purchasing information

Purchasing information shall describe the product to be purchased, including, where appropriate,

a) requirements for approval of product, procedures, processes and equipment,

b) requirements for qualification of personnel, and

c) quality management system requirements.

The organization shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.

7.4.3 Verification of purchased product

The organization shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.

Where the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification arrangements and method of product release in the purchasing information.

7.5 Production and service provision

7.5.1 Control of production and service provision

The organization shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include, as applicable,

a) the availability of information that describes the characteristics of the product,

b) the availability of work instructions, as necessary,

c) the use of suitable equipment,

d) the availability and use of monitoring and measuring equipment,

e) the implementation of monitoring and measurement, and

f) the implementation of product release, delivery and post-delivery activities.

7.5.2 Validation of processes for production and service provision

The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.

Validation shall demonstrate the ability of these processes to achieve planned results.

The organization shall establish arrangements for these processes including, as applicable,

a) defined criteria for review and approval of the processes,

b) approval of equipment and qualification of personnel,

c) use of specific methods and procedures,

d) requirements for records (see 4.2.4), and

e) revalidation.

7.5.3 Identification and traceability

Where appropriate, the organization shall identify the product by suitable means throughout product realization.

The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.

Where traceability is a requirement, the organization shall control the unique identification of the product and maintain records (see 4.2.4).

NOTE In some industry sectors, configuration management is a means by which identification and traceability are maintained.

7.5.4 Customer property

The organization shall exercise care with customer property while it is under the organization's control or being used by the organization. The organization shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer and maintain records (see 4.2.4).

NOTE Customer property can include intellectual property and personal data.

7.5.5 Preservation of product

The organization shall preserve the product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. As applicable, preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.

7.6 Control of monitoring and measuring equipment

The organization shall determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization shall establish processes to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment shall

a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);

b) be adjusted or re-adjusted as necessary;

c) have identification in order to determine its calibration status;

d) be safeguarded from adjustments that would invalidate the measurement result;

e) be protected from damage and deterioration during handling, maintenance and storage.

In addition, the organization shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. The organization shall take appropriate action on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained (see 4.2.4).

When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.

8 Measurement, analysis and improvement

8.1 General

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed

a) to demonstrate conformity to product requirements,

b) to ensure conformity of the quality management system, and

c) to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extent of their use.

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

As one of the measurements of the performance of the quality management system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements. The methods for obtaining and using this information shall be determined.

NOTE Monitoring customer perception can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.

8.2.2 Internal audit

The organization shall conduct internal audits at planned intervals to determine whether the quality management system

a) conforms to the planned arrangements (see 7.1), to the requirements of this International Standard and to the quality management system requirements established by the organization, and

b) is effectively implemented and maintained.

An audit programme shall be planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.

Records of the audits and their results shall be maintained (see 4.2.4).

The management responsible for the area being audited shall ensure that any necessary corrections and corrective actions are taken without undue delay to eliminate detected non conformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results (see 8.5.2).

NOTE See ISO 19011 for guidance.

8.2.3 Monitoring and measurement of processes

The organization shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes. These methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate.

NOTE When determining suitable methods, it is advisable that the organization consider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their impact on the conformity to product requirements and on the effectiveness of the quality management system.

8.2.4 Monitoring and measurement of product

The organization shall monitor and measure the characteristics of the product to verify that product requirements have been met. This shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.

Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).

The release of product and delivery of service to the customer shall not proceed until the planned arrangements (see 7.1) have been satisfactorily completed, unless otherwise approved by a relevant authority and, where applicable, by the customer.

8.3 Control of nonconforming product

The organization shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.

Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:

a) by taking action to eliminate the detected nonconformity;

b) by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;

c) by taking action to preclude its original intended use or application;

d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

8.4 Analysis of data

The organization shall determine, collect and analyse appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate where continual improvement of the effectiveness of the quality management system can be made. This shall include data generated as a result of monitoring and measurement and from other relevant sources.

The analysis of data shall provide information relating to

a) customer satisfaction (see 8.2.1),

b) conformity to product requirements (see 8.2.4),

c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and

d) suppliers (see 7.4).

8.5 Improvement

8.5.1 Continual improvement

The organization shall continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.

8.5.2 Corrective action

The organization shall take action to eliminate the causes of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.

A documented procedure shall be established to define requirements for

a) reviewing nonconformities (including customer complaints),

b) determining the causes of nonconformities,

c) evaluating the need for action to ensure that nonconformities do not recur,

d) determining and implementing action needed,

e) records of the results of action taken (see 4.2.4), and

f) reviewing the effectiveness of the corrective action taken.

8.5.3 Preventive action

The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

A documented procedure shall be established to define requirements for

a) determining potential nonconformities and their causes,

b) evaluating the need for action to prevent occurrence of nonconformities,

c) determining and implementing action needed,

d) records of results of action taken (see 4.2.4), and

e) reviewing the effectiveness of the preventive action taken.

Annex A
(informative)

Correspondence between ISO 9001:2008 and ISO 14001:2004

Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004

ISO 9001:2008		ISO 14001:2004	
Introduction (title only)			Introduction
General	0.1		
Process approach	0.2		
Relationship with ISO 9004	0.3		
Compatibility with other management systems	0.4		
Scope (title only)	1	1	Scope
General	1.1		
Application	1.2		
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Quality management system (title only)	4	4	Environmental management system requirements (title only)
General requirements	4.1	4.1	General requirements
Documentation requirements (title only)	4.2		
General	4.2.1	4.4.4	Documentation
Quality manual	4.2.2		
Control of documents	4.2.3	4.4.5	Control of documents
Control of records	4.2.4	4.5.4	Control of records
Management responsibility (title only)	5		
Management commitment	5.1	4.2	Environmental policy
		4.4.1	Resources, roles, responsibility and authority
Customer focus	5.2	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
		4.6	Management review
Quality policy	5.3	4.2	Environmental policy
Planning (title only)	5.4	4.3	Planning (title only)
Quality objectives	5.4.1	4.3.3	Objectives, targets and programme(s)
Quality management system planning	5.4.2	4.3.3	Objectives, targets and programme(s)
Responsibility, authority and communication (title only)	5.5		
Responsibility and authority	5.5.1	4.1	General requirements
		4.4.1	Resources, roles, responsibility and authority
Management representative	5.5.2	4.4.1	Resources, roles, responsibility and authority
Internal communication	5.5.3	4.4.3	Communication
Management review (title only)	5.6	4.6	Management review
General	5.6.1	4.6	Management review
Review input	5.6.2	4.6	Management review
Review output	5.6.3	4.6	Management review

Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004 (*continued*)

ISO 9001:2008		ISO 14001:2004	
Resource management (title only)	6		
Provision of resources	6.1	4.4.1	Resources, roles, responsibility and authority
Human resources (title only)	6.2		
General	6.2.1	4.4.2	Competence, training and awareness
Competence, training and awareness	6.2.2	4.4.2	Competence, training and awareness
Infrastructure	6.3	4.4.1	Resources, roles, responsibility and authority
Work environment	6.4		
Product realization (title only)	7	4.4	Implementation and operation (title only)
Planning of product realization	7.1	4.4.6	Operational control
Customer-related processes (title only)	7.2		
Determination of requirements related to the product	7.2.1	4.3.1	Environmental aspects
		4.3.2	Legal and other requirements
		4.4.6	Operational control
Review of requirements related to the product	7.2.2	4.3.1	Environmental aspects
		4.4.6	Operational control
Customer communication	7.2.3	4.4.3	Communication
Design and development (title only)	7.3		
Design and development planning	7.3.1	4.4.6	Operational control
Design and development inputs	7.3.2	4.4.6	Operational control
Design and development outputs	7.3.3	4.4.6	Operational control
Design and development review	7.3.4	4.4.6	Operational control
Design and development verification	7.3.5	4.4.6	Operational control
Design and development validation	7.3.6	4.4.6	Operational control
Control of design and development changes	7.3.7	4.4.6	Operational control
Purchasing (title only)	7.4		
Purchasing process	7.4.1	4.4.6	Operational control
Purchasing information	7.4.2	4.4.6	Operational control
Verification of purchased product	7.4.3	4.4.6	Operational control
Production and service provision (title only)	7.5		
Control of production and service provision	7.5.1	4.4.6	Operational control
Validation of processes for production and service provision	7.5.2	4.4.6	Operational control
Identification and traceability	7.5.3		
Customer property	7.5.4		
Preservation of product	7.5.5	4.4.6	Operational control
Control of monitoring and measuring equipment	7.6	4.5.1	Monitoring and measurement
Measurement, analysis and improvement (title only)	8	4.5	Checking (title only)
General	8.1	4.5.1	Monitoring and measurement
Monitoring and measurement (title only)	8.2		
Customer satisfaction	8.2.1		
Internal audit	8.2.2	4.5.5	Internal audit
Monitoring and measurement of processes	8.2.3	4.5.1	Monitoring and measurement
		4.5.2	Evaluation of compliance

Table A.1 — Correspondence between ISO 9001:2008 and ISO 14001:2004 (*continued*)

ISO 9001:2008		ISO 14001:2004	
Monitoring and measurement of product	8.2.4	4.5.1	Monitoring and measurement
		4.5.2	Evaluation of compliance
Control of nonconforming product	8.3	4.4.7	Emergency preparedness and response
		4.5.3	Nonconformity, corrective action and preventive action
Analysis of data	8.4	4.5.1	Monitoring and measurement
Improvement (title only)	8.5		
Continual improvement	8.5.1	4.2	Environmental policy
		4.3.3	Objectives, targets and programme(s)
		4.6	Management review
Corrective action	8.5.2	4.5.3	Nonconformity, corrective action and preventive action
Preventive action	8.5.3	4.5.3	Nonconformity, corrective action and preventive action

Table A.2 — Correspondence between ISO 14001:2004 and ISO 9001:2008

ISO 14001:2004		ISO 9001:2008	
Introduction			Introduction (title only)
		0.1	General
		0.2	Process approach
		0.3	Relationship with ISO 9004
		0.4	Compatibility with other management systems
Scope	1	1	Scope (title only)
		1.1	General
		1.2	Application
Normative references	2	2	Normative references
Terms and definitions	3	3	Terms and definitions
Environmental management system requirements (title only)	4	4	Quality management system (title only)
General requirements	4.1	4.1	General requirements
		5.5	Responsibility, aut hority an d communication (title only)
		5.5.1	Responsibility and authority
Environmental policy	4.2	5.1	Management commitment
		5.3	Quality policy
		8.5.1	Continual improvement
Planning (title only)	4.3	5.4	Planning (title only)
Environmental aspects	4.3.1	5.2	Customer focus
		7.2.1	Determination of requirements rel ated to the product
		7.2.2	Review of requirements related to the product
Legal and other requirements	4.3.2	5.2	Customer focus
		7.2.1	Determination of requirements rel ated to the product
Objectives, targets and programme(s)	4.3.3	5.4.1	Quality objectives
		5.4.2	Quality management system planning
		8.5.1	Continual improvement
Implementation and operation (title only)	4.4	7	Product realization (title only)
Resources, roles, responsibility and authority	4.4.1	5.1	Management commitment
		5.5.1	Responsibility and authority
		5.5.2	Management representative
		6.1	Provision of resources
		6.3	Infrastructure
Competence, training and awareness	4.4.2	6.2.1	(Human resources) General
		6.2.2	Competence, training and awareness
Communication	4.4.3	5.5.3	Internal communication
		7.2.3	Customer communication
Documentation	4.4.4	4.2.1	(Documentation requirements) General
Control of documents	4.4.5	4.2.3	Control of documents

Table A.2 — Correspondence between ISO 14001:2004 and ISO 9001:2008 (*continued*)

ISO 14001:2004		ISO 9001:2008	
Operational control	4.4.6	7.1	Planning of product realization
		7.2	Customer-related processes (title only)
		7.2.1	Determination of requirements related to the product
		7.2.2	Review of requirements related to the product
		7.3.1	Design and development planning
		7.3.2	Design and development inputs
		7.3.3	Design and development outputs
		7.3.4	Design and development review
		7.3.5	Design and development verification
		7.3.6	Design and development validation
		7.3.7	Control of design and development changes
		7.4.1	Purchasing process
		7.4.2	Purchasing information
		7.4.3	Verification of purchased product
		7.5	Production and service provision (title only)
		7.5.1	Control of production and service provision
		7.5.2	Validation of processes for production and service provision
		7.5.5	Preservation of product
Emergency preparedness and response	4.4.7	8.3	Control of nonconforming product
Checking (title only)	4.5	8	Measurement, analysis and improvement (title only)
Monitoring and measurement	4.5.1	7.6	Control of monitoring and measuring equipment
		8.1	(Measurement, analysis and improvement) General
		8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
		8.4	Analysis of data
Evaluation of compliance	4.5.2	8.2.3	Monitoring and measurement of processes
		8.2.4	Monitoring and measurement of product
Nonconformity, corrective action and preventive action	4.5.3	8.3	Control of nonconforming product
		8.4	Analysis of data
		8.5.2	Corrective action
		8.5.3	Preventive action
Control of records	4.5.4	4.2.4	Control of records
Internal audit	4.5.5	8.2.2	Internal audit
Management review	4.6	5.1	Management commitment
		5.6	Management review (title only)
		5.6.1	General
		5.6.2	Review input
		5.6.3	Review output
		8.5.1	Continual improvement

Annex B
(informative)

Changes between ISO 9001:2000 and ISO 9001:2008

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or ~~Deletion~~ (D)	Amended text
Foreword	Para 2	D + A	International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, ~~Part 3~~ Part 2.
Foreword	Para 3, Sentence 1	A	The main task of technical committees is to prepare International Standards.
Foreword	Para 4, Sentence 1	D + A	Attention is drawn to the possibility that some of the elements of this ~~International Standard~~ document may be the subject of patent rights.
Foreword	Para 5	D	~~International Standard~~ ISO 9001 was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.
Foreword	Para 6	D	~~This third edition of ISO 9001 cancels and replaces the second edition (ISO 9001:1994) together with ISO 9002:1994 and ISO 9003:1994. It constitutes a technical revision of these documents. Those organizations which have used ISO 9002:1994 and ISO 9003:1994 in the past may use this International Standard by excluding certain requirements in accordance with 1.2.~~
		A	This fourth edition cancels and replaces the third edition (ISO 9001:2000), which has been amended to clarify points in the text and to enhance compatibility with ISO 14001:2004.
Foreword	Para 7	D	~~The title of ISO 9001 has been revised in this edition and no longer includes the term "Quality assurance". This reflects the fact that the quality management system requirements specified in this edition of ISO 9001, in addition to quality assurance of product, also aim to enhance customer satisfaction.~~
Foreword	Para 8	D	Annexes A ~~and B of this International Standard are for information only.~~
Foreword	New para 7	A	Details of the changes between the third edition and this fourth edition are given in Annex B.
0.1	Para 1, Sentence 2	D	~~The design and implementation of an organization's quality management system is influenced by varying needs, particular objectives, the products provided, the processes employed and the size and structure of the organization.~~
		A	The design and implementation of an organization's quality management system is influenced by a) its organizational environment, change in that environment, and the risks associated with that environment; b) its varying needs; c) its particular objectives; d) the products it provides; e) the processes it employs; f) its size and organizational structure.
	Sentence 3	Now a new para	It is not the intent of this International Standard to imply uniformity in the structure of quality management systems or uniformity of documentation.
0.1	Para 4	A	This International Standard can be used by internal and external parties, including certification bodies, to assess the organization's ability to meet customer, statutory and regulatory requirements applicable to the product, and the organization's own requirements.
0.2	Para 2	D + A	For an organization to function effectively, it has to ~~identify~~ determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (*continued*)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or ~~Deletion~~ (D)	Amended text
0.2	Para 3	A	The application of a system of processes within an organization, together with the identification and interactions of these processes, and their management to produce the desired outcome, can be referred to as the "process approach".
0.3	Para 1	D + A	~~The present editions of~~ ISO 9001 and ISO 9004 ~~have been developed as a consistent pair of~~ are quality management system standards which have been designed to complement each other, but can also be used independently. ~~Although the two International Standards have different scopes, they have similar structures in order to assist their application as a consistent pair.~~
0.3	Para 3	D + A	~~ISO 9004 gives a guidance on a wider range of objectives of a quality management system than does ISO 9001, particularly for the continual improvement of an organization's overall performance and efficiency, as well as its effectiveness. ISO 9004 is recommended as a guide for organizations whose top management wishes to move beyond the requirements of ISO 9001, in pursuit of continual improvement of performance. However, it is not intended for certification or for contractual purposes.~~ At the time of publication of this International Standard, ISO 9004 is under revision. The revised edition of ISO 9004 will provide guidance to management for achieving sustained success for any organization in a complex, demanding, and ever changing, environment. ISO 9004 provides a wider focus on quality management than ISO 9001; it addresses the needs and expectations of all interested parties and their satisfaction, by the systematic and continual improvement of the organization's performance. However, it is not intended for certification, regulatory or contractual use.
0.4	Para 1	D + A	~~This International Standard has been aligned with ISO 14001:1996 in order to enhance the compatibility of the two standards for the benefit of the user community.~~ During the development of this International Standard, due consideration was given to the provisions of ISO 14001:2004 to enhance the compatibility of the two standards for the benefit of the user community. Annex A shows the correspondence between ISO 9001:2008 and ISO 14001:2004.
1.1	Bullet a)	A	a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and
	Bullet b)	A	b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
	Note	D	~~NOTE In this International Standard, the term "product" applies only to the product intended for, or required by, a customer.~~
		A	NOTE 1 In this International Standard, the term "product" only applies to a) a product intended for, or required by, a customer, b) any intended output resulting from the product realization processes.
	New Note 2	A	NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.
1.2	Para 3	A	Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.
2	Para 1	D + A	~~The following normative document contains provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.~~
		A	The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.
		D + A	ISO 9000:~~2000~~2005, *Quality management systems — Fundamentals and vocabulary*

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (*continued*)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or ~~Deletion~~ (D)	Amended text
3	Para 1	D + A	For the purposes of this document ~~International Standard~~, the terms and definitions given in ISO 9000 apply.
3	Paras 2, 3	D	~~The following terms, used in this edition of ISO 9001 to describe the supply chain, have been changed to reflect the vocabulary currently used:~~ ~~**supplier → organization → customer**~~ ~~The term "organization" replaces the term "supplier" used in ISO 9001:1994, and refers to the unit to which this International Standard applies. Also, the term "supplier" now replaces the term "subcontractor".~~
4.1	Bullet a)	D + A	a) ~~identify~~ determine the processes needed for the quality management system and their application throughout the organization (see 1.2),
4.1	Bullet e)	A	e) monitor, measure where applicable, and analyse these processes, and
4.1	Para 4	D + A	Where an organization chooses to outsource any process that affects product conformity ~~with~~ to requirements, the organization shall ensure control over such processes. The type and extent of control to be applied to these outsourced processes shall be defined within the quality management system.
4.1	Note 1	D + A	NOTE 1 Processes needed for the quality management system referred to above ~~should~~ include processes for management activities, provision of resources, product realization, ~~and~~ measurement, analysis and improvement.
4.1	New Notes 2 & 3	A	NOTE 2 An "out sourced process" is a process that the organization needs for its quality management system and which the organization chooses to have performed by an external party.
			NOTE 3 Ensuring control over outsourced processes does not absolve the organization of the responsibility of conformity to all customer, statutory and regulatory requirements. The type and extent of control to be applied to the outsourced process can be influenced by factors such as a) the potential impact of the outsourced process on the organization's capability to provide product that conforms to requirements, b) the degree to which the control for the process is shared, c) the capability of achieving the necessary control through the application of 7.4.
4.2.1	Bullet c)	A	c) documented procedures and records required by this International Standard, and
4.2.1	Bullet d)	A + D	d) documents, including records, ~~needed~~ determined by the organization to be necessary to ensure the effective planning, operation and control of its processes. ~~and~~
4.2.1	Bullet e)	D	~~e) records required by this International Standard (see 4.2.4).~~
4.2.1	Note 1	A	NOTE 1 Where the term "documented procedure" appears within this International Standard, this means that the procedure is established, documented, implemented and maintained. A single document may address the requirements for one or more procedures. A requirement for a documented procedure may be covered by more than one document.
4.2.3	Bullet f)	A	f) to ensure that documents of external origin determined by the organization to be necessary for the planning and operation of the quality management system are identified and their distribution controlled, and
4.2.4	Para 1	D + A	Records ~~shall be~~ established ~~and maintained~~ to provide evidence of conformity to requirements and of the effective operation of the quality management system shall be controlled. ~~Records shall remain legible, readily identifiable and retrievable.~~ The organization shall establish a documented procedure ~~shall be established~~ to define the controls needed for the identification, storage, protection, retrieval, retention ~~time~~ and disposition of records. Records shall remain legible, readily identifiable and retrievable.
5.5.2	Para 1	A	Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes
6.2.1	Para 1	A + D	Personnel performing work affecting conformity to product ~~quality~~ requirements shall be competent on the basis of appropriate education, training, skills and experience.
	New Note	A	NOTE Conformity to product requirements can be affected directly or indirectly by personnel performing any task within the quality management system.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (*continued*)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or ~~Deletion~~ (D)	Amended text
6.2.2	Clause title	A + D	Competence, training and awareness ~~and training~~
6.2.2	Bullets a) & b)	A + D	a) determine the necessary competence for personnel performing work affecting conformity to product ~~quality~~ requirements, b) where applicable, provide training or take other actions to ~~satisfy these needs~~ achieve the necessary competence,
6.3	Bullet c)	A	c) supporting services (such as transport, communication or information systems).
6.4	New Note	A	NOTE The term "work environment" relates to those conditions under which work is performed including physical, environmental and other factors (such as noise, temperature, humidity, lighting or weather).
7.1	Bullet b)	A + D	b) the need to establish processes and documents, and to provide resources specific to the product;
7.1	Bullet c)	A	c) required verification, validation, monitoring, measurement, inspection and test activities specific to the product and the criteria for product acceptance;
7.2.1	Bullet c) Bullet d), New Note	D + A D + A A	c) statutory and regulatory requirements ~~related~~ applicable to the product, and d) any additional requirements ~~determined~~ considered necessary by the organization. NOTE Post-delivery activities include, for example, actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.
7.3.1	New Note	A	NOTE Design and development review, verification and validation have distinct purposes. They can be conducted and recorded separately or in any combination, as suitable for the product and the organization.
7.3.2	Para 2	D + A	~~These~~ The inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous and not in conflict with each other.
7.3.3	Para 1	D + A	The outputs of design and development shall be ~~provided in a form that enables~~ in a form suitable for verification against the design and development input and shall be approved prior to release.
7.3.3	Bullet b)	D	b) provide appropriate information for purchasing, production and ~~for~~ service provision,
7.3.3	New Note	A	NOTE Information for production and service provision can include details for the preservation of product.
7.3.7	Paras 1 & 2	No text change. Paras now merged	Design and development changes shall be identified and records maintained. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered. Records of the results of the review of changes and any necessary actions shall be maintained (see 4.2.4).
7.5.1	Bullet d)	D + A	d) the availability and use of monitoring and measuring ~~devices~~ equipment,
7.5.1	Bullet f)	A	f) the implementation of product release, delivery and post-delivery activities.
7.5.2	Para 1	D + A	The organization shall validate any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement ~~This includes any processes where~~ and, as a consequence, deficiencies become apparent only after the product is in use or the service has been delivered.
7.5.3	Para 2	A	The organization shall identify the product status with respect to monitoring and measurement requirements throughout product realization.
7.5.3	Para 3	D + A	Where traceability is a requirement, the organization shall control ~~and record~~ the unique identification of the product and maintain records (see 4.2.4).
7.5.4	Para 1, Sentence 3 Note	D + A A	If any customer property is lost, damaged or otherwise found to be unsuitable for use, ~~this shall be reported to the customer and records maintained~~ the organization shall report this to the customer and maintain records (see 4.2.4). NOTE Customer property can include intellectual property and personal data.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (*continued*)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or ~~Deletion~~ (D)	Amended text
7.5.5	Para 1	D + A	The organization shall preserve the ~~conformity of~~ product during internal processing and delivery to the intended destination in order to maintain conformity to requirements. ~~This~~ As applicable, preservation s hall inc lude ident ification, handling, pac kaging, st orage and pro tection. Preservation shall also apply to the constituent parts of a product.
7.6	Title	D + A	Control of monitoring and measuring ~~devices~~ equipment
7.6	Para 1	D + A	The organization shall determine the monitoring and measurement to be under taken and the monitoring a nd measuring ~~de vices~~ equ ipment needed t o provide e vidence of conf ormity of product to determined requirements ~~(see 7.2.1)~~.
7.6	Bullet a)	A	a) be calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded (see 4.2.4);
7.6	Bullet c)	D + A	~~c) be identified to enable the calibration status to be determined;~~ c) have identification in order to determine its calibration status;
7.6	Para 4, Sentence 3	Now new para 5, without change.	Records of the results of calibration and verification shall be maintained (see 4.2.4).
7.6	Note	D + A	~~NOTE See ISO 10012-1 and ISO 10012-2 for guidance~~ NOTE Confirmation of the ability of computer software to satisfy the intended application would typically include its verification and configuration management to maintain its suitability for use.
8.1	Bullet a)	D + A	a) to demonstrate conformity ~~of the product~~ to product requirements,
8.2.1	New Note	A	NOTE Monitoring customer perception can include obt aining input from s ources suc h as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.
8.2.2	Para 2 Sentence 3	A	The s election of auditors and conduct of au dits sha ll ensu re objectivity and im partiality of t he audit process.
8.2.2	New Para 3	A	A documented procedure shall be established to define the responsibilities and requirements for planning and conducting audits, establishing records and reporting results.
8.2.2	Para 3	Now para 4 D + A	~~The res ponsibilities and requirem ents f or planning and conduc ting audit s, and f or repor ting results and maintaining records (see 4.2.4) shall be defined in a documented procedure.~~ Records of the audits and their results shall be maintained (see 4.2.4).
8.2.2	Para 4 Sentence 1	Now para 5 A	The m anagement res ponsible f or t he area being audit ed s hall ens ure t hat an y necess ary corrections and corrective ac tions are t aken wit hout undue delay t o eliminat e det ected nonconformities and their causes.
8.2.2	Note	D + A	NOTE ~~See ISO 10011-1, ISO 10011-1 and ISO 10011-3.~~ See ISO 19011 for guidance.
8.2.3	Para 1 Sentence 3	D	When planned result s are not achie ved, c orrection and corr ective act ion shall be t aken, as appropriate~~, to ensure conformity of the product~~.
8.2.3	New Note	A	NOTE When det ermining suit able m ethods, it is advisab le that the organization c onsider the type and extent of monitoring or measurement appropriate to each of its processes in relation to their im pact on t he conformity to product req uirements and on t he effectiveness of the quality management system.
8.2.4	Para 1	A	The orga nization sha ll m onitor and m easure the charact eristics of the produc t to v erify t hat product requirem ents ha ve be en met . This shall be car ried out at appr opriate stages of t he product realization process in accordance with the planned arrangements (see 7.1). Evidence of conformity with the acceptance criteria shall be maintained.
	Para 2	D + A	~~Evidence of conformity with the acceptance criteria shall be maintained.~~ Records shall indicate the person(s) authorizing release of product for delivery to the customer (see 4.2.4).
	Para 3	D + A	~~Product r elease and ser vice deliv ery~~ The release of product an d deliv ery of s ervice to the customer shall not pro ceed unt il t he planned ar rangements (s ee 7.1) have been satisfactorily completed, unles s ot herwise appro ved b y a rele vant aut hority and, wher e appli cable, b y t he customer.

Table B.1 — Changes between ISO 9001:2000 and ISO 9001:2008 (*continued*)

ISO 9001:2000 Clause No.	Paragraph/ Figure/ Table/ Note	Addition (A) or ~~Deletion~~ (D)	Amended text
8.3	Para 1, Sentence 2	D + A	~~The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.~~ A documented procedure shall be established to define the controls and related responsibilities and authorities for dealing with nonconforming product.
8.3	Para 2	A	Where applicable, the organization shall deal with nonconforming product by one or more of the following ways:
8.3	New bullet d)	A	d) by taking action appropriate to the effects, or potential effects, of the nonconformity when nonconforming product is detected after delivery or use has started.
	Para 3	Moved to be Para 4	~~Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4)~~
	Para 4	Moved to be Para 3	When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements. Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).
	Para 5	Now new bullet d)	~~When nonconforming product is detected after delivery or use has started, the organization shall take action appropriate to the effects, or potential effects, of the nonconformity~~.
8.4	Bullet b)	D + A	b) conformity to product requirements ~~(see 7.2.1)~~ (see 8.2.4),
	Bullet c)	A	c) characteristics and trends of processes and products, including opportunities for preventive action (see 8.2.3 and 8.2.4), and
	Bullet d)	A	d) suppliers (see 7.4).
8.5.2	Para 1	D + A	The organization shall take action to eliminate the ~~cause~~ causes of nonconformities in order to prevent recurrence.
8.5.2	Bullet f)	A	f) reviewing the effectiveness of the corrective action taken.
8.5.3	Bullet e)	A	e) reviewing the effectiveness of the preventive action taken.
Annex A	All	D + A	*Updated to reflect ISO 9001:2008 versus ISO 14001:2004*
Annex B	All	D + A	*Updated to reflect ISO 9001:2008 versus ISO 9001:2000*
Bibliography	New and amended references	D + A	*Updated to reflect new standards (including ISO 9004, currently under revision), new editions of standards, or withdrawn standards.*

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